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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,017	12/12/2003	Terry F. Plasse	03223109	2314

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EXAMINER

EBRAHIM, NABILA G

ART UNIT PAPER NUMBER

1618

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/735,017	PLASSE, TERRY F.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 13-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Amendments of claims filed 10/17/05 have been entered

Status of claims:

Claims 1-12 are cancelled.

Claims 13-33 are pending in the application.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 13, 14, 22, 25, 29, 30-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,7,9,10,11,13, and 14 of U.S. Patent No. 6703418. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '418 claims a method of treating a patient with symptomatic HIV infection to stimulate weight gain in the patient,

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which comprises administering to the patient a pharmaceutical composition comprising delta-9-tetrahydrocannabinol orally, in orally administered dosages between about 2.5 mg to 20 mg daily. The claims of the instant application are overlapping with the discussed claims of '418.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaupel et al. and Noyes et al. Vaupel et al teach that delta-9-THC stimulates food consumption in normal subjects. The claims differ in that they are drawn to the treatment of symptomatic HIV-infected patients. It would have been obvious to any person with skill in the art to employ a drug known for its ability to induce food consumption in healthy subjects for the same purpose in subjects infected with HIV or those suffering from any other disorder.

Additionally, Noyes et al. teach the use of delta-9-THC for appetite stimulation in cancer patients. Again, the claims differ in that they are drawn to the treatment of symptomatic HIV-infected patients. Cancer patients undergoing chemotherapy are immuno-suppressed as are symptomatic HIV infected patients and therefore are subject to many of the same symptoms as are patients with

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symptomatic HIV infections. Therefore, in view of the prior art it would have been obvious to any person who is skilled in the art to employ delta-9-THC for the purpose of the instant invention.

Since it is well known in the art that delta-9-THC induces an increased appetite, one of ordinary skill would have been motivated to employ delta-9-THC in the treatment of healthy patients as well as those suffering from any disease in which it is desirable to stimulate the appetite, absent evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patent number 5055446 (Alexander et al.) which teaches a method to improve survival of patients during sepsis by diet composition, and Patent number 6887893 (Kurakata et al.) and patent number teaches Methods and compositions for treatment and prevention of tumors, tumor-related disorders and cachexia.

### ***Response to arguments***

Applicant's arguments filed 10/17/05 have been fully considered but they are not persuasive.

#### ***Applicant argues that:***

Vaupel discusses administering delta-9-tetrahydrocannabinol to dogs and subsequent observations.

Noyes discusses the psychological effects of delta-9-THC in advanced cancer patients. The most prominent effects were sedation and mental clouding. Increased appetite (not

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weight gain) was reported after dosing with 10 mg of THC but less commonly described after 29 mg doses.

***In response to these arguments:***

It is the position of the Examiner to emphasize that the USPTO concern with a composition is its novelty. What the applicant is arguing is the intent of use of the compound claimed, however the intent of use is not of weight since the prior art compositions would be at least capable of performing said use. In addition, it is within a skilled artisan and even the general public without specific skills in the art to understand the relation between enhancing the appetite and gaining weight.

In addition the dose disclosed by the prior art of 10 mg is within the dose recited in the claims which is 2.5 to 20 mg. The amount of the delta-9-THC, which will vary with the condition being treated, the stage of the advancement of the condition, and the type and concentration of formulation applied. Appropriate amounts in any given instance will be readily apparent to those skilled in the art or capable of determination by routine experimentation. It is also known that claiming of a new use, new function, new dose or unknown property does not necessarily render the claim patentable.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

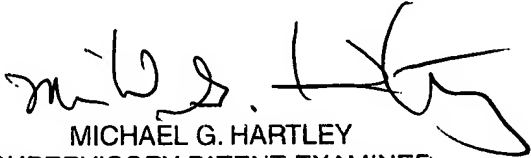
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

3/24/06



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER